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K042040

510(k) Summary

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Trade Name:	TriActiv® System
Common Name:	Distal Occlusion Balloon Catheter
Classification Name:	Device, Coronary Saphenous Vein Bypass Graft, Temporary For Embolization Protection *(per 21 CFR section 870.1250)*
Regulatory Class:	Class II
Device Product Code:	NFA
510(k) Number:	K042040
Predicate Device:	K013913 - PercuSurge GuardWire® Temporary Occlusion and Aspiration System
Date Prepared:	February 14, 2005

Description of Device

The TriActiv® System is a temporary balloon occlusion embolic protection device used during percutaneous coronary intervention of diseased saphenous vein grafts ranging from 3.0mm to 5.0mm in diameter. The device is comprised of four principal components: ShieldWire™ Temporary Occlusion Balloon Guidewire ("balloon guidewire), Balloon Inflation Syringe, FlushCath™ Catheter ("flush catheter"), and AutoStream™ Flow Control ("flow control"). There are also five subcomponents or accessories included in the TriActiv® System: the split tube introducer, guidewire plug and installer, AutoStream™ Flow Control Power Supply, TriActiv® Tuohy, and flush catheter attachment tool. All TriActiv® System components are supplied sterile and for single use only with exception of the AutoStream™ Flow Control Power Supply which is non-sterile and reusable. The balloon guidewire is advanced through the hospital supplied 7F guide catheter (without sideholes) prior to percutaneous coronary intervention of a saphenous vein graft (SVG) and positioned just past the target lesion.

The balloon is inflated with carbon dioxide (CO_2) gas, creating a protected space between the guide catheter and the balloon. Once the balloon is inflated and vessel occlusion is confirmed, PTCA and/or stenting can be performed over the balloon guidewire. Immediately after intervention, the flush catheter is attached to the balloon guidewire and advanced into the graft. With the flush catheter positioned just proximal to the balloon, the flow control delivers saline through the flush catheter to gently wash the vessel and remove any debris generated during the intervention through the guide catheter into a collection bag. The TriActiv® System has been designed to extract at a greater rate than it infuses to prevent aortic embolization. Once the physician is satisfied with the amount of debris removed from the vessel, the protection balloon is deflated and the device is removed.

1. ShieldWire™ Temporary Occlusion Balloon Guidewire

The ShieldWire™ Temporary Occlusion Balloon Guidewire is a single-use 0.014-inch hypo-tube guidewire with a shapeable radiopaque floppy tip and an integrated proprietary latex distal protection balloon used to occlude a 3.0mm to 5.0mm vessel. It is available in 190cm and 340cm lengths. The latex balloon is mounted over two inflation holes, which allow the balloon to be inflated with CO_2 through the central lumen of the hypo-tube lumen. The use of CO_2 as an inflation medium, allows for rapid inflation and deflation of the protection balloon. The balloon is inflated using the Balloon Inflation Syringe. Under fluoroscopic visualization, the physician may adjust the balloon size with the inflation syringe in order to fully occlude vessels between 3.0mm and 5.0mm. The guidewire is coated to reduce surface friction and allow for easier delivery of interventional devices. A radiopaque tip stop is soldered to the distal segment just proximal to the balloon to protect the balloon from damage due to a PTCA or stent catheter and to provide visualization under fluoroscopy. The split tube introducer is an accessory used to protect the balloon and floppy tip during introduction through the TriActiv® Tuohy valve. The proximal end of the guidewire is sealed with a removable guidewire plug to prevent debris or fluid from entering the lumen during catheter exchanges. Just prior to balloon inflation, the guidewire plug is removed from the proximal end of the guidewire. An additional guidewire plug is provided with the system within the guidewire plug installer, which protects the plug and aids with insertion of the plug into the guidewire.

2. Balloon Inflation Syringe

The Balloon Inflation Syringe is used to inflate the guidewire occlusion balloon with CO_2. It is mainly comprised of a 3.0cc syringe with a pediatric Tuohy-Borst valve, which locks the syringe onto the guidewire. A volume control knob allows for incremental increases in CO_2. The syringe is pre-filled with enough USP grade CO_2 to occlude a 3.0mm to 5.0mm diameter vessel. To inflate the balloon, the plunger is depressed and released. A volume control knob may be twisted in a clockwise direction to increase the balloon diameter to occlude blood flow in larger vessels up to 5.0mm.

3. AutoStream™ Flow Control

The AutoStream™ Flow Control is a single use AC powered fluid flow control system with integrated tubing. The flow control incorporates mechanical pumps for fluid infusion and debris extraction as well as the tubing used to connect the flow control to the FlushCath™ Catheter (infusion) and the TriActiv® Tuohy (extraction). The sterile flow control is powered by a reusable non-sterile power supply that is kept out of the sterile field. The flow control user interface incorporates 3 buttons and a digital numeric readout. A simple electronic circuit with a pre-programmed microprocessor controls all the functions of the unit. The flush catheter delivers infusate while extraction occurs simultaneously. The AutoStream™ Flow Control Power Supply is a non-sterile, reusable power cord used to provide power from an electrical outlet to the flow control. The TriActiv® Tuohy is a multiple port Tuohy-Borst valve that is attached to the guide catheter by a rotating luer and allows interventional access. It also provides an angiographic interface and port for extraction of debris.

4. FlushCath™ Catheter

The FlushCath™ Catheter is a side attachable, 3F catheter with a radiopaque marker to aid in placement. The flush catheter is used to wash debris from the target vessel, which is then extracted into the collection bag. Attachment is achieved by pressing the guidewire into a 2 cm slit in the side of the catheter tip thereby placing the guidewire into the lumen of the catheter, creating a short mono-rail. The flush catheter attachment tool facilitates this process.

Intended Use of Device

The TriActiv® System is indicated for use in conjunction with percutaneous coronary intervention (PCI), using a 7F guide catheter (without side holes), of diseased saphenous vein coronary bypass grafts ranging from 3.0mm to 5.0mm in diameter. The TriActiv® System is intended to protect the distal coronary vasculature by trapping and extracting thrombotic and atheromatous debris liberated during PCI. The safety and effectiveness of this device as an embolic protection system has not been established in the cerebral, carotid, or peripheral vasculature; native coronary arteries; or for treatment of patients with acute myocardial infarction.

Technological Characteristics

The technological characteristics of the TriActiv® System are substantially equivalent to the predicate device in that they are both coronary embolic protection devices which trap and extract debris loosened during percutaneous coronary intervention of diseased saphenous vein bypass grafts. In addition, both systems utilize a 0.014-inch diameter temporary occlusion balloon guidewire. The primary technological differences include the CO_2 inflated distal occlusion balloon to improve speed of inflation and deflation, automated extraction to eliminate manual "syringing" of debris, and automated flushing during extraction to assist in debris removal.

Non-Clinical and Clinical Summary

Non-clinical verification and validation of the TriActiv® System has been performed through extensive in vitro bench testing, biocompatibility testing, software validation, package integrity testing, shelf life testing, and in vivo animal studies. Results of this testing indicate that the TriActiv® System design meets all specifications and intended use.

Clinical evaluation of the TriActiv® System was conducted in a non-randomized European CE Mark study, a U.S. pilot study, and the randomized PRIDE (PRotection during Saphenous Vein Graft Intervention to Prevent Distal Embolization) Study. Enrollment in PRIDE began on 12/4/01 and ended on 3/26/04 (duration of enrollment was 2 years, 3 months, and 22 days). The last patient visit occurred in late April 2004 and the database was locked on 7/2/04. There were 68 sites in the United States and 10 sites in Europe who participated in PRIDE. Refer to Table 1 for a breakdown of patients according to treatment group. The PRIDE Study involved a total of 894 vein graft patients (including roll-in, Cohort 1 and Cohort 2 patients). Due to the quick adoption of embolic protection as the standard of care for SVG intervention early on in the PRIDE Trial, there was a very low rate of enrollment in Cohort 1. Cohort 1 evaluated 33 patients treated with the TriActiv® System vs. 29 patients treated with no embolic protection. The total number of patients in Cohort 1 was too small to statistically analyze and therefore no analysis was performed. PRIDE Study Cohort 2 consisted of 631 patients total; 313 randomized to the TriActiv® arm and 318 randomized to the Active Control arm (either FilterWire® EX Embolic Protection System or GuardWire® Plus Temporary Occlusion and Aspiration System).

Table 1: Distribution of Patients According to Randomized Treatment and Treatment Actually Received

Treatment Group	Number of Patients As Assigned/Randomized	Number of Patients As Received
All Groups	894	893
Roll-In	201	200
TriActiv® Cohort 1	33	33
Placebo Cohort 1	29	31
TriActiv® Cohort 2	313	310
Active Control Cohort 2	318	319

The 30-day MACE rates in Cohort 1 are as follows: 18.3% (6/33) for TriActiv® and 10.2% (3/29) for placebo. Due to small number of patients in Cohort 1, statistical analysis to assess superiority is not appropriate, and therefore was not performed.

The 30-day MACE rates in Cohort 2 are as follows: 11.2% (35/313) for TriActiv® and 10.1% (32/318) for Active Control. The non-inferiority hypothesis was based on the Cohort 2 data and required that the MACE rate through 30-days for the TriActiv® group versus the Active Control group not be statistically different when tested to a delta of 6%. The PRIDE Study met its non-inferiority hypothesis with a p-value of 0.023 relative to the delta of 6.0%. The upper one-sided 95% confidence bound on the difference in 30-

day MACE rates was 0.0515; hence, the PRIDE Study would have achieved non-inferiority to the active control with a delta as small as 5.2%.

Table 2: Principal Results (Intent to Treat Analysis)

	Roll-in	TriActiv® (N=33) n (%)	Placebo (N=29) n (%)	TriActiv® (N=313) n (%)	Active Control (N=318) n (%)	Difference (95% CB)[1]
MACE to 30 days	29 (14.4%)	6 (18.2%)	3 (10.3%)	35 (11.2%)	32 (10.1%)	1.1% (5.2%)
Death	2 (1.0%)	0 (0%)	0 (0%)	4 (1.3%)	2 (0.6%)	0.7% (1.9%)
Cardiac	1 (0.5%)	0 (0%)	0 (0%)	4 (1.3%)	2 (0.6%)	0.7% (1.9%)
Non Cardiac[2]	1 (0.5%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0% (-)
MI	26 (12.9%)	5 (15.2%)	3 (10.3%)	31 (9.9%)	28 (8.8%)	1.1% (4.9%)
Q wave	4 (2.0%)	0 (0%)	0 (0%)	4 (1.3%)	1 (0.3%)	1.0% (2.1%)
Non-Q wave	22 (11.0%)	5 (15.2%)	3 (10.3%)	27 (8.6%)	27 (8.5%)	0.1% (3.8)
Emergent CABG	1 (0.5%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0% (-)
TVR	4 (2.0%)	2 (6.1%)	0 (0%)	5 (1.6%)	4 (1.3%)	0.3% (1.9%)
MACE-in-hospital	25 (12.4%)	5 (15.2%)	3 (10.3%)	31 (9.9%)	29 (9.1%)	0.8 (4.6%0
Stroke-in-hospital	1 (0.5%)	0 (0%)	0 (0%)	1 (0.3%)	1 (0.3%)	0% (0.7%)
Stroke-discharge to end of study	1 (0.5%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0% (-)
Hemorrhagic/vascular complications-in-hosp	23 (11.4%)	1 (3.0%)	2 (6.9%)	34 (10.9%)	17 (5.4%)	5.5% (9.1%)
7 F	2 (6.9%)	1 (7.1%)	1 (16.7%)	9 (6.3%)	8 (5.5%)	0.8% (5.4%)
8 F	19 (12.0%)	0 (0%)	0 (0%)	23 (15.4%)	5 (3.9%)	11.5% (17.2%)
Transfusion	16 (8.0%)	1 (3.0%)	0 (0%)	24 (7.7%)	11 (3.5%)	4.2% (7.2%)
7 F	2 (6.9%)	1 (7.1%)	0 (0%)	5 (3.5%)	5 (3.5%)	0.1% (3.6%)
8 F	13 (8.2%)	0 (0.0%)	0 (0%)	17 (11.4%)	3 (2.3%)	9.1% (13.9%)
Device Success	181 (90.0%)	31 (93.9%)	N/A	293 (94.5%)	-	-
Procedure Success/Patient[3]	173/200 (86.5%)	27/32 (84.4%)	25/29 (86.2%)	278/311 (89.4%)	286/316 (90.5%)	1.1% (5.1%)
Lesion Success/Lesion[4]	197/200 (98.5%)	32/32 (100%)	27/29 (93.1%)	308/311 (99.0%)	313/315 (99.4%)	0.3% (1.5%)

[1] Difference in percentages between TriActiv Cohort 2 and the active control (one-sided 95% upper confidence bound on the difference)
[2] Non-cardiac death is not a MACE as defined in the protocol, but is shown for comparison to cardiac death, which is a MACE as defined in the protocol
[3] Final stenosis < 50% by QCA for all lesions and no in-hospital MACE.
[4] Final stenosis < 50% by QCA

Design Changes during PRIDE

There were two versions of the TriActiv® System that were used during the PRIDE Trial. The study started with version 1 and completed with version 2. Based on actual devices received among Cohort 1 and Cohort 2 patients, 273 patients received version 1 and 70 patients received version 2. The two versions of the device differ with respect to the infusion/extraction control. Version 1 used a large, AC-powered, multi-use Drive Console. Additionally, within version 1, there were several design modifications to the ShieldWire™ guidewire and FlushCath™ Catheter. The changes within version 1 and from version 1 to version 2 were made to: (1) improve the product overall; (2) address physician requests to improve ease of use; and (3) improve manufacturability outcomes.

Version 2 replaced the Drive Console with a smaller, AC-powered, single-use, sterile, tabletop AutoStream™ Flow Control. Along with the introduction of the AutoStream™ Flow Control, a gender change was made to the extraction port on the TriActiv® Tuohy to accommodate the AutoStream™ Flow Control tubing. The Drive Console and the AutoStream™ Flow Control have the same infusion and extraction flow rates. The change to the AutoStream™ Flow Control and TriActiv® Tuohy do not adversely affect product performance specifications, principle of operation, intended use (medical indication), or labeling (except for changes to the Instructions for Use as a result of the design change).

The impact of the design changes on patient outcomes from the PRIDE Trial was assessed and found to have no negative impact on MACE, blood loss requiring transfusion, device malfunction/failure, or "any complication".

Conclusion

Kensey Nash Corporation considers the TriActiv® System to be substantially equivalent to the predicate device GuardWire® Temporary Occlusion and Aspiration System (K013913) legally marketed by Medtronic AVE based on its intended use, target population, technical features and the results on non-clinical and clinical evaluation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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MAR 2 3 2005

Ms. Robin M. Fatzinger, RAC
V.P. of Clinical & Regulatory Affairs
Kensey Nash Corporation
55 E. Uwchlan Avenue
Exton, PA 19341

Re: K042040
Trade/Device Name: TriActiv® System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: II
Product Code: NFA
Dated: February 14, 2005
Received: February 15, 2005

Dear Ms. Fatzinger:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Bachman

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K042040

Device Name: TriActiv® System

Indications for Use:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over-the-Counter Use_____
(per 21 CFR 801.109)

Donna R Bachmann

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K042040